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ATTORNEY DOCKET NO.: 2002834-0232 (Bacterial Delivery DIV2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caplan, et al. Examiner: Not yet assigned
Serial No.: 10/728,323 Art Unit: Not yet assigned
Filing Date: December 4, 2003
Title: MICROBIAL DELIVERY SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

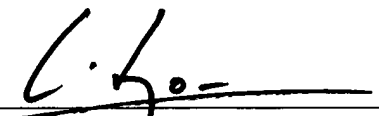
TRANSMITTAL LETTER

Enclosed are the following documents:

1. Transmittal Letter (1 page);
2. 1st Form PTO-1449 (2 pages); Cited Art (20 references)
3. 2nd Form PTO-1449 (2 pages); Cited Art (22 references)
4. Supplemental Information Disclosure Statement;
5. Limited Recognition Under 37 CFR § 10.9(b); and
6. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,


Charles E. Lyon, D.Phil
Agent for Applicant
Limited Recognition Under 37 CFR §10.9(b)

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53 State Street
Boston, MA 02109
(617) 248-5000
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Dated: January 29, 2004

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<u>Sandra Saccocia</u>	
Typed or Printed Name of person signing certificate	



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P.O. Box 1450
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Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or
☒ A *supplemental* Information Disclosure Statement.

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1-29-04 Sandra Saccoccia
Date Signature

Sandra Saccoccia

Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☐ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
 - ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with an asterisk is included;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

☐ Does not contain non-English language citations;

☐ Does contain non-English language citations, of which the following is a concise explanation:

☐ Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .


The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



Charles E. Lyon, D.Phil.

Agent for Applicant

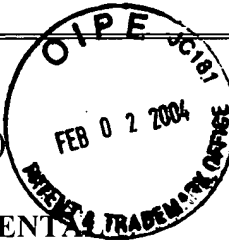
Limited Recognition Under 37 CFR §10.9(b)

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Dated: January 22, 2004

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PTO-1449 (REV. 8-83)	 U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET: 2002834-0232	IN RE APPLICATION NO.: 10/728,323
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		APPLICANT: Caplan, et al.	
		FILING DATE: December 4, 2003	GROUP:

U.S. PATENT DOCUMENTS					
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	6,218,371	Krieg et al.	April 17, 2001	514	44
	5,061,790	Elting et al.	October 29, 1991	530	402
	4,959,314	Mark et al.	September 25, 1990	435	69.1
	4,849,404	Iwai et al.	July 18, 1989	514	2
	4,658,022	Knowles et al.	April 14, 1987	530	402

U.S. PATENT APPLICATIONS					
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

OTHER DOCUMENTS	
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Del Val, et al., "Thioredoxin Treatment Increases Digestibility and Lowers Allergenicity of Milk", <i>J. Allergy Clin. Immunol.</i> 103(4): 690-697, 1999.
	Hoyne, et al., "Peptide-Mediated Regulation of the Allergic Immune Response", <i>Immunol. Cell Biol.</i> 74(2): 180-186, 1996.
	Vailes, et al., "Fine Specificity of B-Cell Epitopes on Felis Domesticus Allergen I (Fel d I): Effect of Reduction and Alkylation or Deglycosylation of Fel d I Structure and Antibody Binding", <i>J. Allergy Clin. Immunol.</i> 93(1): 22-33, 1994.
	Burns, et al., "Selective Reduction of Disulfides by Tris (2-Carboxyethyl) Phosphine", <i>J. Org. Chem.</i> 56(8): 2648-2650, 1991.
	Gray, et al., "Echistatin Disulfide Bridges: Selective Reduction and Linkage Assignment", <i>The Protein Society</i> , 1749-1755, 1993.

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Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Gray, et al., "Disulfide Structures of Highly Bridged Peptides: A New Strategy for Analysis", <i>The Protein Society</i> , 1732-1748, 1993.
	Herbert, et al., "Reduction and Alkylation of Proteins in Preparation of Two-Dimensional Map Analysis: Why, When, and How?" <i>Electrophoresis</i> , 22: 2046-2057, 2001.
	Nakamura, et al., "Mass Spectrometric-Based Revision of the Structure of a Cysteine-Rich Peptide Toxin with Gamma-Carboxyglutamic Acid, TxVIIA, from the Sea Snail, Conus Textile", <i>Protein Science</i> , 5(3): 524-530, 1996.
	Olsson, et al., "Contribution of Disulphide Bonds to Antigenicity of Lep d 2, the Major Allergen of the Dust Mite <i>Lepidoglyphus Destructor</i> ", <i>Molecular Immunology</i> , 35: 1017-1023, 1998.
	Smith, et al., "Localization of Antigenic Sites on Der p 2 Using Oligonucleotide-Directed Mutagenesis Targeted to Predicted Surface Residues", <i>Clinical and Experimental Allergy</i> , 27: 593-599, 1997.
	Smith, et al., "Recombinant Allergens for Immunotherapy: A Der p 2 Variant with Reduced IgE Reactivity Retains T-Cell Epitopes", <i>J. Allergy Clin. Immunol.</i> 101(3): 423-425, 1998.
	Smith, et al., "Reduction in IgE Binding to Allergen Variants Generated by Site-Directed Mutagenesis: Contribution of Disulfide Bonds to the Antigenic Structure of the Major House Dust Mite Allergen Der p 2", <i>Molecular Immunology</i> , 33(4/5): 399-405, 1996.
	Watson, et al., "Trapping and Identification of Folding Intermediates of Disulfide Bond-Forming Proteins Based on Cyanylation, Cleavage, and Analysis by Mass Spectrometry", http://www.abrf.org/JBT/Articles/JBT0014/JBT0014.html ." Pages 1-12.
	Wu, et al., "A Novel Methodology for Assignment of Disulfide Bond Pairing in Proteins", <i>Protein Science</i> , 6(2): 391-398, 1997.
	Zhou, et al., "Assignment of Disulfide Bonds in Proteins by Partial Acid Hydrolysis and Mass Spectrometry", <i>Journal of Protein Chemistry</i> , 9(5): 523-532, 1990.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

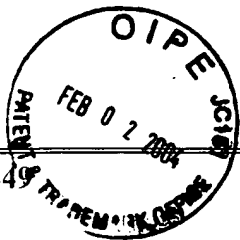
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				FILING DATE: December 4, 2003		GROUP:	

U.S. PATENT DOCUMENTS					
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,888,799	Curtiss III	March 30, 1999		
	5,830,463	Duke, et al.	November 3, 1998		
	5,389,368	Gurtiss III	February 14, 1995		

U.S. PATENT APPLICATIONS					
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	CA 2 158 047	Canada	15 September 1994		
	CA 2 157 596	Canada	29 September 1994		
	JP 07095887	Japan	11 April 1995		
	JP 06253851	Japan	13 September 1994		
	WO 00/54803	PCT	21 September 2000		
	WO 99/25387	PCT	27 May 1999		
	WO 94/20614	PCT	15 September 1994		

OTHER DOCUMENTS	
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Burks, et al., "Epitope Specificity of the Major Peanut Allergen, Ara h II", <i>J. Allergy Clin. Immunol.</i> 95 : 607-611, 1995.
	Gayler, et al., "Biosynthesis, cDNA and Amino Acid Sequences of a Precursor of Conglutin δ , A Sulphur-Rich Protein from <i>Lupinus Angustifolius</i> ", <i>Plant Molecular Biology</i> , 15 : 879-893, 1990.



PTO-1449
(REV. 8-83)

U.S. Department of
Commerce
Patent and Trademark Office

ATTY. DOCKET:
2002834-0232

IN RE
APPLICATION NO.:
10/728,323

**SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**
(Use several sheets if necessary)

APPLICANT: Caplan, et al.

FILING DATE:
December 4, 2003

GROUP:

Examiner's
Initials

Citation (Including Author, Title, Date, Pertinent Pages, Etc.)

Ichikawa, et al., "Solution Structure of Der f 2, the Major Mite Allergen for Atopic Disease", *J. Mol. Chem.*, **273**: 356-360, 1998.

Medaglini, et al., "Mucosal and Systemic Immune Responses to a Recombinant Protein Expressed on the Surface of the Oral Commensal Bacterium *Streptococcus Gordonii* After Oral Colonization", *Proceedings of the National Academy of Sciences of the United States of America*, **92**(15): 6868-6872, 1995.

Nishiyama, et al., "Analysis of the IgE-epitope of Der f 2, a Major Mite Allergen, by in vitro Mutagenesis", *Mol. Immunol.*, **32**: 1021-1029, 1995.

Nishiyama, et al., "Effects of Amino Acid Variations in Recombinant Der f II on its Human IgE and Mouse IgG Recognition", *Int. Arch. Allergy Immunol.*, **105**: 62-69, 1994.

Takai, et al., "Effect of Proline Mutations in the Major House Dust Mite Allergen Der f 2 on IgE-binding and Histamine-releasing Activity", *Eur. J. Biochem.*, **267**: 6650-6656, 2000.

Takai, et al., "Non-anaphylactic Combination of Partially Deleted Fragments of the Major House Dust Mite Allergen Der f 2 for Allergen-specific Immunotherapy", *Mol. Immunol.*, **36**: 1055-1065, 1999.

Takai, et al., "Determination of the N- and C-terminal Sequences to Bind Human IgE of the Major House Dust Mite Allergen Der f 2 and Epitope Mapping for Monoclonal Antibodies", *Mol. Immunol.*, **34**: 255-261, 1997.

Takai, et al., "Engineering of the Major House Dust Mite Allergen Der f 2 for Allergen-specific Immunotherapy", *Nat. Biotechnol.*, **15**: 754-758, 1997.

Vrtala, et al., "Humoral Immune Responses to Recombinant Tree Pollen Allergens (Bet v 1 and Bet v II) in Mice: Construction of a Live Oral Allergy Vaccine", *International Archives of Allergy and Immunology*, **107**: (1-3): 290-294, 1995.

EMBL Accession No. L77197 (March 1996)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.